DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 0 1 - 0 2

2. STATE: WV

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
January 1, 2001

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42 CFR § 441.35

7. FEDERAL BUDGET IMPACT:
a. FFY 2001 $345,000
b. FFY 2002 $345,000

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 3.1-E
Page 1, 2 and 3

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 3.1-E
Page 1, 2, and 3

10. SUBJECT OF AMENDMENT:
Coverage of multivisceral transplant following Medicare guidelines.

11. GOVERNOR'S REVIEW *(Check One)*:

☑ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:
Phillip A. Lynch

13. TYPED NAME:
Phillip A. Lynch

14. TITLE:
Acting Commissioner

15. DATE SUBMITTED:
3-5-01

16. RETURN TO:
Phillip A. Lynch, Acting Commissioner
Bureau for Medical Services
350 Capitol Street, Room 251
Charleston, WV 25301

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 3/6/01

18. DATE APPROVED: 4/20/01

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 1/1/01

20. SIGNATURE OF REGIONAL OFFICIAL: Claudette V Campbell

21. TYPED NAME: CLAUDETTE V CAMPBELL

22. TITLE: ASSOCIATE REGIONAL ADMINISTRATOR DIVISION OF MEDICAID & STATE OPERATIONS

23. REMARKS:

Instructions on Back

State/Territory: West Virginia

STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

Organ transplant services are covered when generally considered safe, effective and medically necessary; when no alternatives medical treatment as recognized by the medical community is available. The transplant must be utilized for the management of disease as a recognized standard treatment in the medical community and must not be of an investigational or research nature and must be used for end-stage diseases, not as prophylactic treatment.

Coverage procedures:

The following organ transplants are covered for Medicaid recipients:

Heart Transplant
Adult Liver Transplant
Pediatric Liver Transplant
Bone Marrow Transplant
Kidney Transplant
Pancreas/Kidney Transplant
Lung Transplant - single and double
Cornea Transplant
Heart/Lung Transplant
Small Intestine/Multivisceral

These procedures are not covered when any two covered procedures are performed in combination except under the following conditions:

(1) If the primary organ defect caused damage to a second organ and transplant of the primary organ will eliminate the disease process, and

(2) If the damage to the second organ will compromise the outcome of the transplant of the primary organ, multiple organ transplantation may be considered.

Organ Transplant Procurement:

Organ procurement organizations perform or coordinate the retrieving, preserving and transporting of organs and maintains a system of locating prospective recipients for available organs.

Organ procurement organizations must have their organ procurement services covered under Medicare and Medicaid. These include certification as a "qualified" organ procurement organization (OPO) and designation as the OPO for a particular service area.

Coverage Patient Selection Criteria:

Patient selection criteria is based upon a critical medical need for transplantation and a maximum likelihood of successful clinical outcome. All other medical and surgical therapies that might be expected to yield both short and long term survival must have been tried or considered. Patient selection criteria must include at a minimum the following finding:

(1) Current medical therapy has failed and the patient has failed to respond to appropriate therapeutic management.

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(2) The patient is not in an irreversible terminal state.

(3) The transplant is likely to prolong life and restore a range of physical and social function suited to activities of daily living.

Coverage - Facilities: Hospitals providing transplant services must be certified for participation in Title XVIII, Medicare, for the specific transplant procedure. Procedures may be performed out of state only when the authorized transplant cannot be performed in West Virginia because the service is not available or, due to capacity limitations, the transplant cannot be performed in the necessary time period.

Criteria applicable to transplant services and facilities in West Virginia also apply to out-of-state transplant services and facilities.

General medical indications for specific organ transplants are as follow:

Bone Marrow

For the treatment of certain diseases where it has come to represent a standard approach to treatment of the disease such as for some leukemias. Not approved for the treatment of diseases which the Bureau considers to still be of an investigative or research nature and when there is no proven significant benefit.

Heart

Cardiomyopathy which is end-stage or irreversible where medical management can no longer restore patient to activities of daily living. Homogenic transplants only (no artificial devices or primates).

Heart/Lung

Severe, irreversible, lung disease with secondary cardiac failure when lung transplant alone would not restore adequate cardiac function. Malignant neoplasms of the lung that are primary or secondary are excluded.

Kidney

End Stage Renal Disease.

Pancreas/Kidney

Medicaid will cover whole organ pancreas transplants only if performed on the same day or following a covered kidney transplant.

Performed to induce an insulin independent, euglycemic state in diabetic patients. This procedure is limited to those patients with severe secondary complication of diabetes, including kidney failure. It is performed on patients with labile diabetes and hypoglycemic unawareness.

Lung

Single - Severe, irreversible, benign lung disease that is severely restricting activities of daily living and no longer amenable to standard medical treatment. Cardiac failure may or may not be present.

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Double - Severe, irreversible, benign lung disease that is severely restricting activities of daily living and no longer amenable to standard medical treatment. The significant factor is the presence of a disease that typically includes infection of a chronic nature, for example, Cystic Fibrosis.

Liver

End Stage Liver Disease, non-malignant in etiology.

1. Acute, fulminant liver necrosis/failure such as seen in certain toxic states, for example, acetaminophen ingestion in toxic amounts with an expected fatal outcome without transplantation.

2. Chronic liver failure where the complications of encephalopathy for ascites and/or variceal bleeding or other complications are no longer amenable to or controlled by recognized medical management.

Small Intestine/Multivisceral

Coverage includes intestinal transplantation alone; combined liver-intestinal transplantation; multivisceral transplantation: stomach, duodenum, pancreas, liver and intestine. Limited to patients who have failed total parental nutrition (TPN). TPN failure as defined by Medicare is: impending or overt failure of TPN; induced liver injury; thrombosis of the major central venous channels; jugular, subclavian and femoral veins; frequent (2 or more per year requiring hospitalization) line infection and sepsis; frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN.

Prior Authorization

Prior authorization is necessary for all transplants with the exception of cornea and kidney. Prior authorization is conducted by a private entity under contract with the Bureau.

Additional Coverage-Recipient Under Age 21

Coverage will not be provided for procedures that are experimental, investigational or of unproven benefit. The procedure must be medically necessary and no alternative common medical treatment as recognized by the medical community is available or effective with outcomes that are at least comparable.

In determining whether a particular procedure falls into the category of experimental or investigational, criteria to be considered include:

(1) The current and historical judgement of the medical community as evidenced by medical research, studies, journals or treaties.

(2) The extent to which Medicare and private insurers recognize and provide coverage for the procedure.

(3) The current judgment of experts and specialists in the medical specialty area in which the procedure is applicable or utilized.

(4) Effectiveness may be judged by considering criteria such as : a) number of times has the procedure been performed; b) the patient mortality rate and/or long term prognosis; c) the reputation/record of the physicians and hospitals performing the procedure.